

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 3 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**REPLY MEMORANDUM IN SUPPORT OF SUPPLEMENTAL MOTION TO  
EXCLUDE AND NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION AND  
REPLY BRIEF OF JOHN MIKLOS, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Ethicon”) submit this reply memorandum in further support of their supplemental motion to exclude certain opinions of John Miklos, M.D.

**INTRODUCTION**

Rather than respond to the substantive arguments Ethicon raised for excluding Dr. Miklos’s general design-defect opinions, Plaintiffs instead falsely accuse Ethicon of abusing the MDL wave process, ignoring this Court’s previous orders, and “improperly seek[ing] reconsideration of the Court’s *Daubert* ruling with respect to this witness.” (Pls.’ Resp. in Opp’n to Defs.’ Supp. Mot. to Exclude Certain Opinions of John Miklos, M.D. (“Pls.’ Resp.”) (Dkt. 2889) at 3). But Ethicon did not file a motion for reconsideration. Contrary to Plaintiffs’ assertions, the MDL Court’s pretrial orders expressly contemplate—and indeed *require*—filing a *Daubert* motion with respect to the general-causation experts’ opinions on a wave-by-wave basis.

**LAW AND ARGUMENT**

**I. Ethicon's motion is not an improper motion for reconsideration.**

As a threshold matter, Plaintiffs' argument that Ethicon's motion "improperly seeks reconsideration of the Court's *Daubert* ruling" ignores this Court's pretrial orders with respect to the MDL wave process and wrongly suggests that the issues Ethicon raised are the ones that this Court already considered and denied. (Pls.' Resp. at 3).

First, under this Court's Docket Control Orders, Ethicon is limited to filing one *Daubert* motion per general-causation expert with respect to *each wave of cases*, not simply one *Daubert* motion, period, which is what Plaintiffs suggest. Indeed, the Docket Control Order for the Wave 3 cases specifically scheduled new expert disclosure and *Daubert* deadlines for the 200 cases that are unique to Wave 3. *See* Pretrial Order #239 at 4; *see also* Pretrial Order #210. The two *Daubert* documents already filed in this MDL for Waves 1 and 2 do not automatically apply to these 200 Wave 3 cases; indeed, if Ethicon wanted to limit Dr. Miklos' general-causation opinions with respect to these cases, they were *required* to file a *Daubert* motion, or Notice of Adoption, as part of Wave 3.<sup>1</sup>

The fact that the parties adopted their Wave 1 *Daubert* motion relative to Dr. Miklos for Wave 2 is irrelevant; doing so was *not* a requirement of this Court's Docket Control Orders. This Court had not yet ruled on any Wave 1 *Daubert* motions, and thus there was no reason to alter the parties' briefing. Now that this Court *has* had the opportunity to decide some of the previously briefed issues, filing a new motion is not only appropriate, but actually fosters

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<sup>1</sup> Plaintiffs implicitly concede this point by acknowledging that the parties filed a Notice of Adoption for their Wave 1 *Daubert* briefing for use in the Wave 2 cases. *See* Pls.' Resp. at 2. If Plaintiffs were correct, then there would have been no need to file notices of adoption and this Court would never have set new *Daubert* deadlines for the general causation experts in Waves 2 or 3. Moreover, the applicable Pretrial Orders set unique discovery and expert designation deadlines for each Wave. Experts appearing in Wave 1, for example, have routinely submitted revised or new reports in subsequent Waves as new evidence has been developed.

efficiency by avoiding issues that have already been conclusively decided by the Court.<sup>2</sup> Nor is Ethicon precluded from raising new arguments in this motion that were not previously included in the Wave 1 or Wave 2 Motions, which did not apply to any of the 200 Wave 3 cases. There is simply no basis—and Plaintiffs have cited no authority—for concluding that motions filed with respect to those previous waves have any waiver or preclusive effect on the Wave 3 cases.

**II. Plaintiffs do not respond to Ethicon’s arguments for excluding Dr. Miklos’s opinions about design defect.**

Notably, Plaintiffs have chosen not to respond to Ethicon’s arguments with respect to Dr. Miklos’s inadmissible design defect opinions, which include his:

- Opinions that several elements of the TVT Secur are “design flaws” that cause injury to patients, including the mechanism for insertion, difficulty in properly tensioning the mesh, release difficulties, difficulty in removing the insertion device after fixation; fixation tips not staying in place; lower success rates; bladder perforations; and excessive bleeding; and
- Lack of qualifications to opine on these alleged defects that implicate biocompatibility expertise that he does not have.

Ethicon has raised arguments tailored to addressing issues left unresolved by this Court’s Wave 1 ruling on Dr. Miklos’s opinions. For example, in its Wave 1 ruling, the Court declined to “issue a blanket exclusion on all testimony about the defective design” of TVT Secur because it found that Ethicon “provide[d] little detail about the specific opinions at issue or why they are unreliable.” (Memorandum Opinion and Order (*Daubert* Motion re: John Miklos, M.D.), Dkt. 2669, at 6). Ethicon moves to exclude these opinions in Wave 3, providing the additional detail that the Court indicated that it would require to consider the reliability of Dr. Miklos’s design-defect opinions by pointing out, for example, Dr. Miklos’s mere regurgitation of internal Ethicon documents in support of his opinions, instead of scientific evidence; and his failure at his

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<sup>2</sup> To the extent that Ethicon’s supplemental motion addresses some of the issues raised in the Wave 1 and Wave 2 motions, it does so because the Court indicated that it required more specific challenges or the Court did not rule directly on the issue.

deposition to account for the role of surgeon skill in patient outcomes in his design-defect general causation opinions. (*See* Defs.' Mot., Skt. 2847 at 3-5). Plaintiffs have simply chosen not to respond to these additional detailed arguments. Moreover, although Ethicon raised the issue of Dr. Miklos's qualifications to testify as to design-defect issues in its Motion, the Court did not address this issue in its Wave 1 Order. Thus, this issue is still unresolved. Ethicon respectfully submits that Dr. Miklos is *not* qualified to opine on these issues, and his testimony should be excluded for the reasons expressed in its Wave 1 briefing.

Because Plaintiffs fail to respond to any of Ethicon's supplemental arguments for exclusion of Dr. Miklos's design-defect opinions, Ethicon respectfully requests that the Court grant its motion and preclude Dr. Miklos from offering any such opinions at trial.

### **CONCLUSION**

Ethicon respectfully requests the Court grant their Motion to Exclude the Testimony of John Miklos, M.D. for the reasons stated above and in their memorandum of law.

Respectfully Submitted,

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR  
SYSTEMS PRODUCTS LIABILITY  
LITIGATION

Master File No. 2:12-MD-02327  
MDL 2327

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ETHICON WAVE 3 CASES LISTED IN  
EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT  
JUDGE

**CERTIFICATE OF SERVICE**

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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